

### THIS LETTER CONTAINS PROPRIETARY INFORMATION **IN ACCORDANCE WITH 10 CFR 2.390**

March 26, 2013

SMT-2013-012 10 CFR 50.30 10 CFR 50.33 10 CFR 50.34 10 CFR 50.37 10 CFR 170.21

U.S. Nuclear Regulatory Commission ATTN: Document Control Desk Washington, DC 20555

- References: (1) SHINE Medical Technologies, Inc. letter to NRC, dated February 18, 2013, Request for Exemption to Submit Application for Construction Permit in Two Parts (ML13051A007)
  - (2) NRC letter to SHINE Medical Technologies, Inc., dated March 20, 2013, SHINE Medical Technologies, Inc. - Exemption From Certain Requirements of 10 CFR 2.101(a)(5), Regarding the Submission of a Construction Permit Application in Two Parts (TAC No. ME7820) (ML13072B195)

Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit

Pursuant to 10 CFR 50.30, SHINE Medical Technologies, Inc. (SHINE) hereby submits an application for a construction permit to construct a medical isotope facility to be located in Janesville, WI. SHINE is submitting this application for a construction permit in two parts. Via Reference (1), SHINE requested exemption from certain requirements of 10 CFR 2.101, which would allow the submittal of an application for construction permit in two parts, in accordance with 10 CFR 2.101(a)(5). The NRC granted SHINE the exemption via Reference (2).

This first part of SHINE's application provides Preliminary Safety Analysis Report (PSAR) Chapter 2, Site Characteristics, in accordance with 10 CFR 50.34(a)(1); PSAR Chapter 19, Environmental Review, in accordance with 10 CFR 50.30(f); fee information, in accordance with 10 CFR 50.30(e) and 10 CFR 170.21; financial and general information, in accordance with 10 CFR 50.33; and the classified information agreement, in accordance with 10 CFR 50.37. Part two of SHINE's application will include the remaining sections of the PSAR per 10 CFR 50.34(a), and will be submitted in accordance with 10 CFR 2.101(a)(5).

Enclosure 1 provides the non-public (proprietary) version of the SHINE PSAR Chapter 2, Site Characteristics, and PSAR Chapter 19, the Environmental Review. Enclosure 1 is being provided via optical storage media (OSM) as OSM#1.

Enclosure 2 provides the public (non-proprietary) version of the SHINE PSAR Chapter 2, Site Characteristics, and PSAR Chapter 19, the Environmental Review. Enclosure 2 is being provided via OSM as OSM#2.

> Enclosures 1 and 3 of this letter contain proprietary information. Withhold from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

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## THIS LETTER CONTAINS PROPRIETARY INFORMATION IN ACCORDANCE WITH 10 CFR 2.390

OSM#1 and OSM#2 each contain a packing slip file, precisely identifying the contents of the submission for the respective OSM. Packing list software provided by the NRC requests the "Submitter Name" from a pull-down menu, which is populated with a list of utilities. The current configuration of the packing slip software does not allow users to enter new names to the pull-down menu, and thus, SHINE requests the NRC revise the packing slip files contained in OSM#1 and OSM#2 to indicate "SHINE Medical Technologies, Inc." as the "Submitter Name." SHINE has currently chosen the utility name at the top of the pull-down menu listing, with the assumption the NRC can revise the packing slip files without delaying review of the SHINE application for construction permit.

Enclosure 3 provides the non-public (proprietary) version of the SHINE General and Financial Information required for submittal of an application for a construction permit. The SHINE General and Financial Information provides general information, fee information, and the classified information agreement.

Enclosure 4 provides the public (non-proprietary) version of the SHINE General and Financial Information.

Enclosure 5 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information pursuant to 10 CFR 2.390. Enclosures 1 and 3 contain proprietary information. SHINE requests that the NRC withhold Enclosures 1 and 3 from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

If you have any questions, please contact Mr. Jim Costedio, Licensing Manager, at 608/210-1730.

I declare under the penalty of perjury that the foregoing is true and correct. Executed on March 26, 2013.

Very truly yours,

R. Vann Bynum, PhD Chief Operating Officer

R. V. Bym

SHINE Medical Technologies, Inc.

Project No.: PROJ0792

**Enclosures** 

cc: Administrator, Region III, USNRC

Project Manager, USNRC

Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health (w/o Enclosure 1 and Enclosure 3)

Environmental Analysis and Review Specialist, Wisconsin Department of Natural Resources (w/o Enclosure 1 and Enclosure 3)

Enclosures 1 and 3 of this letter contain proprietary information.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

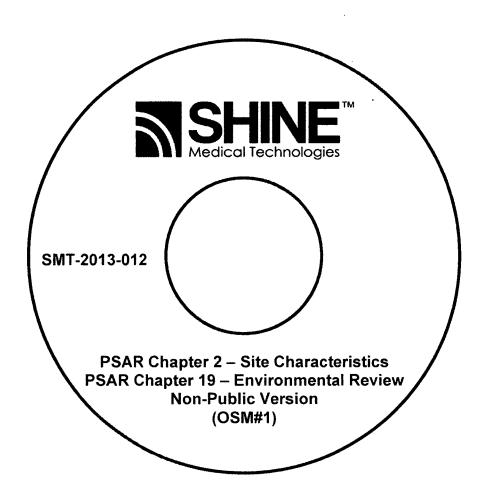
## ENCLOSURE 1 CONTAINS PROPRIETARY INFORMATION IN ACCORDANCE WITH 10 CFR 2.390

#### **ENCLOSURE 1**

SHINE MEDICAL TECHNOLOGIES, INC.

PART ONE OF THE SHINE MEDICAL TECHNOLOGIES, INC.
APPLICATION FOR CONSTRUCTION PERMIT

PSAR CHAPTER 2 – SITE CHARACTERISTICS
PSAR CHAPTER 19 – ENVIRONMENTAL REVIEW
NON-PUBLIC VERSION
(OSM#1)



Enclosures 1 and 3 of this letter contain proprietary information. Withhold from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

#### **ENCLOSURE 2**

## SHINE MEDICAL TECHNOLOGIES, INC.

## PART ONE OF THE SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT

PSAR CHAPTER 2 – SITE CHARACTERISTICS
PSAR CHAPTER 19 – ENVIRONMENTAL REVIEW
PUBLIC VERSION
(OSM#2)



### **ENCLOSURE 4**

## SHINE MEDICAL TECHNOLOGIES, INC.

## PART ONE OF THE SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT

## GENERAL AND FINANCIAL INFORMATION PUBLIC VERSION

2.0	GENERAL INFORMATION IN ACCORDANCE WITH 10 CFR 50.33			
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#### **ATTACHMENTS:**

1.0

INTRODUCTION

- 1. BIOGRAPHIES OF OFFICERS AND DIRECTORS
- 2. STOCKHOLDER RELATIONSHIPS
- 3. CONSTRUCTION COSTS
- 4. SOURCE OF CONSTRUCTION FUNDS
- 5. 2011 AUDITED FINANCIAL STATEMENTS

#### 1.0 INTRODUCTION

SHINE Medical Technologies, Inc. (SHINE) seeks to construct and operate a medical isotope facility for the purpose of producing molybdenum-99 (Mo-99). The decay product of Mo-99, technetium-99m (Tc-99m), is used to perform approximately 16 million imaging procedures in the U.S. each year, and accounts for 80 percent of all nuclear medicine procedures. Tc-99m is used in a wide variety of imaging procedures, including cardiac perfusion imaging (to detect and treat heart disease) and bone scans (to detect cancer metastases). Despite being the world's largest consumer of Tc-99m, the U.S. has no domestic production of Mo-99. Approximately 95 percent of the world's supply of Mo-99 comes from only five nuclear reactors, all of which are greater than 45 years old.

As these reactors age, they must be shut down for repairs and maintenance with increasing frequency, thereby creating supply disruptions. Mo-99, with a half-life of just 66 hours, cannot be stockpiled, and must be produced continuously. Over time, unless a new, reliable production capacity is brought on-line, supply disruptions will become increasingly more frequent.

Without new production capacity, the U.S. will certainly face a Mo-99 shortage in 2016, potentially impacting the health of hundreds of thousands of patients every week. SHINE is submitting a Construction Permit (CP) application to build a medical isotope facility and is currently on schedule to help avert this potential health crisis by meeting its milestone to produce Mo-99 in 2016.

The information required for the CP application to be submitted to the NRC includes general and technical information required to be provided pursuant to 10 CFR 50. SHINE is providing the following general and financial information as Part One of SHINE's CP application for a medical isotope facility:

- General information, in accordance with 10 CFR 50.33;
- Fee information, in accordance with 10 CFR 50.30(e) and 10 CFR 170.21; and
- Classified information agreement, in accordance with 10 CFR 50.37.

## 2.0 GENERAL INFORMATION IN ACCORDANCE WITH 10 CFR 50.33

This part of the CP for SHINE provides details of the applicant's corporate identity and location; applicant's ownership organizations; the types of licenses being applied for; the applicant's financial qualifications and relationships; construction and decommissioning funding assurance; foreign ownership, control, or domination (FOCD) information.

### 2.1 Applicant Information

The applicant's corporate address is:

SHINE Medical Technologies, Inc. 2555 Industrial Drive Monona, Wisconsin, 53713

SHINE Medical Technologies plans to manufacture and sell the medical isotope Mo-99, which is the parent isotope of the diagnostic imaging isotope, Tc-99m. The isotope Tc-99m becomes a "light source" within the body to provide a high-quality view of internal organs. It is primarily used in cardiac stress tests and cancer screening. SHINE will also produce other critical

isotopes, such as I-131 (used to treat cancer and thyroid disorders) and Xe-133 (used to diagnose lung function).

SHINE Medical Technologies is not an individual and is not a partnership.

SHINE is incorporated in the State of Wisconsin and is located in Monona, Wisconsin, at the applicant address listed above. SHINE intends to build its production facility in Janesville, Wisconsin, about 40 miles south of the company's current location. The proposed production facility is located at the address 4025 US Highway 51 South, Janesville, WI 53546.

## 2.2 <u>Corporate Structure, Directors, and Principal Officers</u>

SHINE is the applicant for a CP and will own and operate the facility. This application and the demonstration of financial capability are based on the current corporate structure and financial situation of SHINE.

The facility will be owned by SHINE, which was organized in the State of Wisconsin. The business and affairs of SHINE are managed under the direction of a Board of Directors and through the officers of SHINE. The SHINE board currently consists of seven directors and there are three SHINE executive officers. All of the directors are US citizens except as noted (one director is a citizen of Canada).

The seven current directors are:

Dr. Gregory Piefer, Chief Executive Officer and Director; U.S. Citizen 2555 Industrial Drive Monona, Wisconsin 53713

Dr. Richard Vann Bynum, Chief Operations Officer and Director; U.S. Citizen 2555 Industrial Drive Monona, Wisconsin 53713

Dr. Thomas "Rock" Mackie, Director; Canadian Citizen and U.S. permanent resident 2555 Industrial Drive Monona, Wisconsin 53713

Richard Leazer, Director; U.S. Citizen 2555 Industrial Drive Monona, Wisconsin 53713

Donald J. Whelley, Director; U.S. Citizen 2555 Industrial Drive Monona, Wisconsin 53713

Philip M. Halpern, Director; U.S. Citizen 2555 Industrial Drive Monona, Wisconsin 53713

Christopher Manuele, Director; U.S. Citizen 2555 Industrial Drive Monona, Wisconsin 53713 The three current executive officers of SHINE are:

Dr. Gregory Piefer, Chief Executive Officer; U.S. Citizen 2555 Industrial Drive, Monona, Wisconsin 53713

Dr. Richard Vann Bynum, Chief Operations Officer; U.S. Citizen 2555 Industrial Drive Monona, Wisconsin 53713

Stephen C. Hathaway, Chief Financial Officer; U.S. Citizen 2555 Industrial Drive Monona, Wisconsin 53713

Biographies of the directors and officers are listed in Attachment 1.

## 2.3 <u>Foreign Ownership or Control; Acting as Agent</u>

SHINE is a private, closely held corporation that currently has approximately 25 shareholders. In addition, all employees of SHINE participate in a stock option plan and hold options to purchase shares in the future. To the best of our knowledge, all of our current shareholders holding 1 percent or more of SHINE's stock are U.S. citizens or entities owned or controlled by U.S. citizens. All of our current employees holding stock options are U.S. citizens.

One of the seven directors on SHINE's Board is a Canadian citizen with U.S. permanent resident status. The appointment of one citizen of Canada as a director of SHINE has no material impact on SHINE's current compliance with the requirements regarding FOCD in 10 CFR 50.38.

SHINE is not acting as an agent or representative of another person in filing the CP application.

## 2.4 Class of License

The class of license SHINE is applying for will be a Class 103 license per 10 CFR 50.22 (for commercial and industrial facilities). This application is for the CP for a production facility under 10 CFR 50. Additional future applications will be for the production facility operating license under 10 CFR 50, receipt, possession and use of source material under 10 CFR 40, byproduct material under 10 CFR 30, and special nuclear material under 10 CFR 70. We expect to request an operating license (OL) for a term of 30 years.

### 2.5 <u>Financial Qualification and Stockholder Relationships</u>

As stated above, SHINE currently is a closely-held private corporation with a relatively small number of shareholders. SHINE was formed in 2010, and received additional investment in 2011. The shareholders are either individual investors or are venture capital organizations. Additional information concerning these stockholder relationships is provided in Attachment 2.

SHINE also anticipates obtaining debt financing for the construction of its operations facility.

Additionally, SHINE understands that the NRC may request an established entity or newlyformed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the NRC considers this information appropriate.

### 2.6 Construction Completion

SHINE currently expects to complete construction of the facility by September 30, 2015 at the earliest, and December 31, 2015 at the latest.

## 2.7 <u>Decommissioning</u>

The SHINE business plan anticipates that it will provide for the decommissioning of the facility by establishing an external escrow account in which deposits will be made annually, coupled with a surety method, insurance or some other form of guaranty. This escrow account is intended to provide reasonable assurance that funds will be available to decommission the facility. SHINE will provide a site-specific decommissioning plan with estimated costs and financial assurances to support those costs in its application for an OL.

### 2.8 Construction Costs

The NRC has set forth requirements for applicants for a CP pursuant to 10 CFR 50.33 (f) to submit sufficient information to demonstrate that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. Additionally, the applicant should indicate the source(s) of funds to cover these costs.

The NRC provides financial guidelines in Appendix C to 10 CFR 50 and distinguishes between applicants which are established organizations and those which are newly-formed entities organized primarily for the purpose of engaging in the activity for which the permit is sought. Appendix C provides a guide for the financial data and related information required to establish financial qualifications for CPs. SHINE is considered a newly-formed entity. As stated in Appendix C, the information required by the NRC that will normally be required of applicants which are newly-formed entities will not differ in scope from that required of established organizations.

#### 2.8.1 Estimate of Construction Costs

In accordance with the guidelines of Appendix C to 10 CFR 50, SHINE is providing the construction cost information in Attachment 3.

#### 2.8.2 Source of Construction Funds

SHINE expects to finance the construction of both the production plant and the supporting facility. Such financing will be further supported by guarantees. Additional information relating to sources of construction funds are contained in Attachment 4.

## 2.8.3 Financial Statements, Balance Sheets, and Additional Information

The NRC recognizes that an applicant which is a newly-formed entity will normally not be in a position to submit the usual types of balance sheets and income statements reflecting the results of prior operations. However, the NRC requires the applicant to include in its application

a statement of assets, liabilities, and capital structure. SHINE's 2011 Audited Financial Statements, which are the most recent reports available, are provided in Attachment 5. SHINE will provide an annual financial report each year upon issuance of that report.

The financial protection and indemnity requirements of the Price-Anderson Act, pursuant to Section 170 of The Atomic Energy Act (AEA) of 1954, as amended apply to the SHINE medical isotope facility. The SHINE medical isotope facility is planned to contain up to eight irradiation units, each with a licensed target solution vessel with a fission power of 125 kWth. Consequently, prior to bringing radioactive material on-site, SHINE will obtain \$1 million in insurance to provide financial protection, consistent with 10 CFR 140.13. Prior to operation, SHINE plans to obtain and maintain financial protection of \$1.5 million to cover all eight irradiation units. SHINE requests that the NRC execute an indemnification agreement in accordance with 10 CFR 140.20.

SHINE understands that the NRC may, from time to time, request the applicant, whether an established organization or newly-formed entity, to submit additional or more detailed information respecting its financial arrangements and status of funds if such information is deemed necessary to enable the NRC to determine an applicant's financial qualifications for the license.

## 3.0 FEE INFORMATION IN ACCORDANCE WITH 10 CFR 50.30(e) AND 10 CFR 170.21

SHINE shall pay fees in accordance with 10 CFR 50.30(e) and 10 CFR 170.21 (Schedule of fees for production or utilization facilities, review of standard referenced design approvals, special projects, inspections, and import and export licenses; Facility Category G, Other Production or Utilization Facility). SHINE shall pay "Full Cost" fees for the following categories of services: Application for Construction Permit; Construction Permit, Operating License; Amendment, Renewal, Other Approvals; and Inspections. Additionally, fees will be paid pursuant to Parts 170.1, 170.12, and 170.20.

#### 4.0 CLASSIFIED INFORMATION AGREEMENT IN ACCORDANCE WITH 10 CFR 50.37

SHINE will not allow access to Restricted Data or classified National Security Information until the individual and/or the facility has been approved for access under provisions of 10 CFR 25 and/or 10 CFR 95.

SHINE MEDICAL TECHNOLOGIES, INC.

PART ONE OF THE SHINE MEDICAL TECHNOLOGIES, INC.
APPLICATION FOR CONSTRUCTION PERMIT

GENERAL AND FINANCIAL INFORMATION PUBLIC VERSION

**BIOGRAPHIES OF OFFICERS AND DIRECTORS** 

#### **OFFICERS**

#### **OFFICERS**

#### Dr. Gregory Piefer, President and Chief Executive Officer

Dr. Piefer is the founder of SHINE Medical Technologies, Inc. and presently serves as its CEO. Before this, he served as the president of Phoenix Nuclear Labs, where he managed the development of high-output particle sources. He formerly served as the Chief Technical Officer of Gillware Inc., a leading data recovery and backup company. He holds a PhD in nuclear engineering, and BS degrees in physics and electrical and computer engineering from the University of Wisconsin–Madison.

## Stephen C. Hathaway, Chief Financial Officer

Mr. Hathaway has over 30 years of progressive financial management experience, specializing in medical technology, service and manufacturing environments. Most recently, he served as CFO for TomoTherapy, Inc., a public company with \$200 million in annual sales which designs, manufactures and sells medical equipment to deliver radiation for the treatment of cancer. In 2007, he led the process of taking the company public, raising \$250 million. Prior to that, Mr. Hathaway was the CFO of SurModics, Inc., a medical technology company that he helped take public in 1998.

## Dr. Richard Vann Bynum, Chief Operations Officer

Dr. Bynum has over 30 years' experience in both for profit and national laboratory work and is experienced directing large, high-technology, high-security organizations and projects. His experience includes management of all of Los Alamos National Laboratory's nuclear and non-nuclear facilities, involving a staff of 1,850 people and an annual budget of \$917 million. Dr. Bynum led the organization in a greater than 30 percent improvement in its safety metrics, while reducing staffing and controlling costs. Previously, Dr. Bynum managed a \$200 million/year manufacturing operation where he achieved one of the highest on-time delivery rates in the industry. He also served as the project director for a highly successful \$1.8 billion project to re-establish a critical national security capability, which required frequent interactions with Congressional Members and committees. Dr. Bynum holds a PhD in inorganic chemistry from the University of Alabama and has been certified in Lean Manufacturing by the University of Michigan.

#### **BOARD OF DIRECTORS**

#### Dr. Thomas "Rock" Mackie

Dr. Mackie currently serves as Director of Medical Devices at the Morgridge Institute for Research and as a professor in the departments of Medical Physics, Human Oncology, and Engineering Physics at the University of Wisconsin–Madison. He is the author of more than 130 peer-reviewed publications, 25 patents, and has supervised more than 25 PhD students. With his expertise in radiation therapy treatment planning and intensity-modulated radiotherapy, his group developed the Pinnacle<sup>TM</sup> treatment planning system, now marketed by Philips Medical. He is a co-founder and former Chairman of the Board of TomoTherapy, Inc., a Madison-based company employing 650 people. Dr. Mackie received his B.S. in Physics from the University of Saskatchewan in 1980 and his doctorate in Physics from the University of Alberta in 1984.

## **Dr. Gregory Piefer**

Dr. Piefer is the founder of SHINE Medical Technologies, Inc. and presently serves as its CEO. Before this, he served as the president of Phoenix Nuclear Labs, where he managed the development of high-output particle sources. He formerly served as the Chief Technical Officer to Gillware Inc., a leading data recovery and backup company. He holds a PhD in nuclear engineering, and BS degrees in physics and electrical and computer engineering from the University of Wisconsin–Madison.

## Dr. Richard Vann Bynum

Dr. Bynum has over 30 years' experience in both for profit and national laboratory work and is experienced directing large, high-technology, high-security organizations and projects. His experience includes management of all of Los Alamos National Laboratory's nuclear and non-nuclear facilities, involving a staff of 1,850 people and an annual budget of \$917 million. Dr. Bynum led the organization in a greater than 30 percent improvement in its safety metrics, while reducing staffing and controlling costs. Previously, Dr. Bynum managed a \$200 million/year manufacturing operation where he achieved one of the highest on-time delivery rates in the industry. He also served as the project director for a highly successful \$1.8 billion project to re-establish a critical national security capability, which required frequent interactions with Congressional Members and committees. Dr. Bynum holds a PhD in inorganic chemistry from the University of Alabama and has been certified in Lean Manufacturing by the University of Michigan.

## **BOARD OF DIRECTORS (continued)**

#### Richard Leazer

Richard Leazer was Managing Director of the Wisconsin Alumni Research Foundation prior to his retirement in 2000. He was President of Ohmeda, a medical device and equipment manufacturer, and a division of BOC, from 1988 through 1992. From 1981 to 1988 he was President of Anaquest, a specialty pharmaceutical company and a division of BOC. Currently, Mr. Leazer is a principal in a Madison-based angel investing network, Wisconsin Investment Partners, LLC. Former positions also include President of the WIN Foundation, which sponsors the Wisconsin Venture Fair as well as a Technology luncheon series, and founding President of the Wisconsin Technology Council, an organization working to improve Wisconsin's high technology company environment. He was a Trustee of the Weinert Applied Ventures Program for Entrepreneurship at the UW-Madison School of Business. Mr. Leazer received a bachelor's degree in Business Administration from the University of Iowa in 1963 and an MBA from the Drexel Institute of Technology in 1966.

### Donald J. Whelley

Donald J. Whelley is the Managing Member of DJW Advisors, providing advisory services to institutional and high net worth clients. Don has worked for over thirty years in energy and financial services providing valuation and advisory services and most recently supporting clients investing in other industry sectors including mining and biotech. After graduating with a BS in Accounting from Clarkson University, Don began his professional career working as an auditor for Arthur Andersen. Don's career has included accounting, finance and acquisition work for companies involved in oil and gas, agricultural biotech, broker dealer and syndication of real estate investments and energy consulting. In addition to SHINE, Don served as a Director of GeoResources Inc. (Houston TX), a publicly traded exploration & production company, Board Observer of Dynamis Therapeutics, Inc. (Philadelphia, PA), a private biotech, and currently serves as a Board Observer for Flugen, Inc. (Madison, WI), a private medical device maker/vaccine company, and Advisory Board member of Blue Ocean Consulting, Inc. (Lawrence, KS), an internet software and consulting firm.

#### Philip M. Halpern

Philip M. Halpern is the managing partner of the law firm of Collier, Halpern, Newberg, Nolletti & Bock, LLP, with offices in New York City, White Plains and Stamford, Connecticut. Mr. Halpern is a magna cum laude graduate of Fordham University, where he majored in economics, and is a graduate of Pace University School of Law where he obtained his juris doctor. He is a Fellow of the American Bar Foundation and a member of the Office of Court Administration's Advisory Committee on Civil Practice, the Association of the Bar of the City of New York, the Committee on Federal Judiciary for the New York State Bar Association, the American Bar Association, the New York County Lawyers Association, New York State Trial Lawyers Association, the Association of Trial Lawyers of America, and the Federal Bar Council. Mr. Halpern has been a member of the Advisory Council for the Board of Judges for the Southern District of New York. Mr. Halpern began his legal career in 1980 as a law clerk to a federal judge in the Southern District of New York.

## **BOARD OF DIRECTORS (continued)**

### **Christopher Manuele**

Christopher Manuele was the GM of the Global Nuclear Medicine Supply Chain and the GM of Oncura Inc. at GE Healthcare prior to his retirement in 2008. He is currently a consultant to the Pharmaceutical Industry. He has over 34 years of comprehensive US/International experience in the Finance, Administration, Operations, Development and Commercial Functions. An innovative problem solver with expertise in Lean, Quality Systems, Operational Excellence and the development and bringing to market of new Nuclear Medicine products. He received a BS in Finance from Northern Illinois University in 1973.

SHINE MEDICAL TECHNOLOGIES, INC.

PART ONE OF THE SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT

GENERAL AND FINANCIAL INFORMATION PUBLIC VERSION

STOCKHOLDER RELATIONSHIPS

## **STOCKHOLDER RELATIONSHIPS**

SHINE currently is a closely-held private corporation with a relatively small number of shareholders. The shareholders are either individual investors or are venture capital organizations. To the best of our knowledge, the majority, if not all, of the current shareholders are U.S. citizens, or U.S. entities controlled by U.S citizens.

There are two classes of stock – Common Stock and Series A Preferred Stock. [ Proprietary Information ]

[ Proprietary Information ]

SHINE anticipates seeking additional capital investment as it continues plans for construction of the facility. It is likely that such capital will come from venture capital firms and current and new high net worth individuals. Those additional investments will likely be made under new terms that impose different or additional requirements, such as the right of new investors to appoint certain directors to serve on the board of directors, information rights, and other preferred terms of investment. This Application will be updated as needed to address such changes.

SHINE MEDICAL TECHNOLOGIES, INC.

PART ONE OF THE SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT

GENERAL AND FINANCIAL INFORMATION PUBLIC VERSION

**CONSTRUCTION COSTS** 

## **ESTIMATE OF CONSTRUCTION COSTS**

(a)	Total production plant of	costs	[ Proprietary Information ]
(b)	Support facility costs	•	[ Proprietary Information ]
(c)	Plant equipment		[ Proprietary Information ]
(d)	Nuclear fuel inventory	cost for approximate one year supply	[ Proprietary Information ]
	٦	Total estimated cost	[ Proprietary Information ]

These numbers represent the budgetary estimate based on the conceptual design of the SHINE facility.

SHINE MEDICAL TECHNOLOGIES, INC.

# PART ONE OF THE SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT

GENERAL AND FINANCIAL INFORMATION PUBLIC VERSION

**SOURCE OF CONSTRUCTION FUNDS** 

## SOURCE OF CONSTRUCTION FUNDS

SHINE has obtained financing for its development and construction project using various sources of financing, including equity, debt and government grants. To date, the Company has received commitments as follows:

- 1. Cost sharing agreement with the DOE/NNSA: \$25 million
- 2. Equity financing raised to-date: \$11.4 million
- 3. Alliant Energy shared savings program loan: \$4.8 million
- 4. State of Wisconsin Enterprise Zone Tax Credits: \$11.2 million
- 5. City of Janesville loan packages/guarantees: \$4.6 million
- 6. 90 acres of land for the building site provided by the City of Janesville: \$1.0 million

SHINE is in the process of obtaining an additional equity capital investment from outside investors. It is likely that such capital will come from venture capital firms and current and new high net worth individuals.

SHINE expects to finance the construction of the facility. This will be under either a short-term lease or a debt agreement, or both. SHINE expects to fully own the facility within five years of start-up. At present, SHINE has not yet entered into any financing agreements with financial institutions or other potential sources for such lease or debt financing.

[ Proprietary Information ]

SHINE MEDICAL TECHNOLOGIES, INC.

PART ONE OF THE SHINE MEDICAL TECHNOLOGIES, INC.
APPLICATION FOR CONSTRUCTION PERMIT

GENERAL AND FINANCIAL INFORMATION PUBLIC VERSION

**2011 AUDITED FINANCIAL STATEMENTS** 

### **ENCLOSURE 5**

## SHINE MEDICAL TECHNOLOGIES, INC.

# PART ONE OF THE SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT

**AFFIDAVIT OF RICHARD VANN BYNUM** 



## **AFFIDAVIT OF RICHARD VANN BYNUM**

STATE OF WISCONSIN	)
	) ss
COUNTY OF DANE	)

- I, Richard Vann Bynum, Chief Operating Officer of SHINE Medical Technologies, Inc. (SHINE), do hereby affirm and state:
  - 1. I am authorized to execute this affidavit on behalf of SHINE. I am authorized to review information submitted to or discussed with the Nuclear Regulatory Commission (NRC) and apply for the withholding of information from public disclosure. The purpose of this affidavit is to provide the information required by 10 CFR 2.390(b) in support of SHINE's request for proprietary treatment of certain confidential commercial and financial information submitted in the Construction Permit (CP) application for the SHINE medical isotope facility transmitted by letter SMT-2013-012 with enclosures. SHINE requests that the confidential information contained in Enclosure 1 and Enclosure 3 be withheld from public disclosure in their entirety.
  - 2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.
  - 3. Pursuant to the provisions of paragraph (a)(4) of 10 CFR 2.390, the following is furnished for consideration by the NRC in determining whether the information sought to be withheld from public disclosure should be withheld.
    - a. The information sought to be withheld from public disclosure contained in Enclosure 1 and Enclosure 3 of SMT-2013-012 is owned by SHINE, its affiliates or third parties to whom SHINE has an obligation to maintain its confidentiality. This information is and has been held in confidence by SHINE.
    - b. The information sought to be protected in Enclosure 1 and Enclosure 3 is not available to the public to the best of my knowledge and belief.
    - c. The information contained in both Enclosure 1 and Enclosure 3 is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, confidential financial information,

commercial information or information that is subject to export controls. SHINE limits access to these elements to those with a "need to know," and subject to maintaining confidentiality.

- d. The proprietary information sought to be withheld from public disclosure in Enclosure 1 includes, but is not limited to: structural configuration, primary and supporting systems of the medical isotope facility, process and system locations, and process details. This would include information regarding the types, quantities, and locations of materials stored on site as would be referenced in facility configuration drawings. Public disclosure of the information in Enclosure 1 would create substantial harm to SHINE because it would reveal trade secrets owned by SHINE, its affiliates or third parties to whom SHINE has an obligation to maintain its confidentiality.
- e. Public disclosure of the information in Enclosure 3 would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes and current position. Its use by a competitor could substantially improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.
- f. The information contained in Enclosure 1 and Enclosure 3 of the CP application contained in letter SMT-2013-012 is transmitted to the NRC in confidence and under the provisions of 10 CFR 2.390; it is to be received in confidence by the NRC. The information is properly marked.

Richard Vann Bynum, PhD

COO - SHINE Medical Technologies, Inc.

Date: 3/26/13

Subscribed and sworn to before me, a Notary Public, in and for the county and state above named, this \_\_ 26\_\_ day of March 2013.

Notary Public in and for the State of Wisconsin My Commission expires August 20/3